

DEVELOPMENT OF BION™ TECHNOLOGY FOR FUNCTIONAL ELECTRICAL STIMULATION: HERMETIC PACKAGING

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Abstract - BIONs™ are chronically implanted, individually addressable, single channel electrical stimulators that are now in clinical trials. They receive power and command signals from an externally worn RF transmission coil. The electronic circuitry is packaged in a glass capsule that can be injected through a hypodermic needle to provide distributed multichannel FES systems. The small size (2mm OD x 16mm long), external electrodes and long design life (>10 years) pose a challenge for hermetic sealing and testing. We here describe several novel packaging techniques that have been integrated into a single workstation to enable efficient and reliable production of BION implants.

Keywords - neural prostheses, electrical stimulation, implants, hermetic packaging, glass, tantalum

I. INTRODUCTION

BIONs (BIONic Neurons) are modular, micro miniature implants (Figure 1), each of which provides a long-term, wireless interface between an external electronic controller and a neural function in the body [1,4]. A transmitter coil is placed over a region of the body that contains one or more BIONs, which receive power and command signals by inductive coupling. The first generation of this technology (BION1) produces stimulation pulses with controlled current (0-30mA) and duration (4-512 μ s). BION1 implants have undergone extensive preclinical testing [3]. The materials comprising their electrodes and packaging play a critical role in the biocompatibility and reliability of these implants. BIONs are being used in two ongoing clinical trials that study the therapeutic effects of electrically induced exercise to prevent and reverse disuse atrophy in patients with stroke and osteoarthritis [2].

BION1:

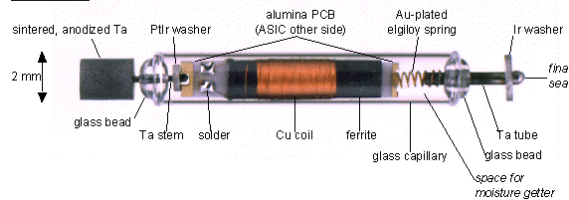


Figure 1. Main components and hermetic packaging scheme for a BION1 implant

The electronic components are protected from body fluids by a capsule made from borosilicate glass

(Kimbel N51A). The circuitry makes electrical contact with the electrodes on either end of the capsule via tantalum feedthroughs that must be sealed hermetically to the glass. One electrode is made from Ta powder that has been sintered onto a Ta stem. It is anodized at the end of the fabrication process to produce a low-leakage capacitor electrode that stores the energy to be released as brief stimulus pulses. The internal end of the stem is welded to a washer made of 90%Pt-10%Ir to provide a stable electromechanical contact with the gold-plated end of the alumina printed circuit board (PCB) that carries the hybrid electronic circuitry. The other electrode is made from iridium to provide a non-polarizing return electrode. It is welded to a Ta feedthrough for compatibility with the glass sealing process. The internal end of this hollow tubular feedthrough is welded to a gold-plated spring that makes electromechanical contact with the opposite end of the electronic subassembly. The tube is initially left open to enable all critical glass-to-Ta and glass-to-glass seals to be leak-tested with helium. It provides access to the inside of the capsule for evacuation and backfilling with an inert gas; then it is welded shut. Because the volume of the capsule is so small, water vapor diffusing through undetectable leaks could reach the condensation point in a matter of weeks. By incorporating a small cylinder of a moisture getter (aluminum silicate in a polymer carrier), the apparent internal volume for moisture is expanded by a factor of up to 5000X [4].

The original fabrication methods were tedious and subject to yield problems. The implant was assembled from three subassemblies, each of which involved a large number of processes that required small parts to be repeatedly handled and remounted as they were transferred among various workstations [3]. Welds and cuts involving metal parts were made using a range of technologies including handheld wire cutters, resistance welds and plasma needle arc welds. We here describe an integrated process for packaging and testing BION implants in one series of steps performed at a single workstation with minimal parts handling.

II. PACKAGE FABRICATION

The steps required to form the implant package according to the new process are listed chronologically in Figure 2. Note that only two technologies are required for all welds and cuts: an infrared CO₂ laser for melting the glass and a Nd:YAG laser for cutting and welding metal. These two technologies are suitable for combining in the close quarters of a single workstation because the laser

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beams can be directed onto the work-in-progress from a distance.

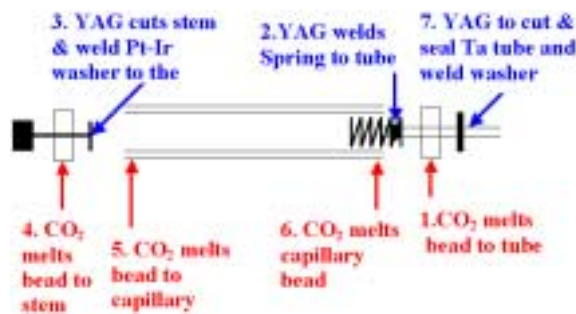


Figure 2. Sequence of steps required to build the BION package.

The sequence of component assembly is shown in Figure 3. The vertical line is broken by arrowheads at steps that require transfer of the partially completed implant to another workstation. Note that all of the steps related to formation and testing of the hermetic package are performed at one integrated workstation, as described below.

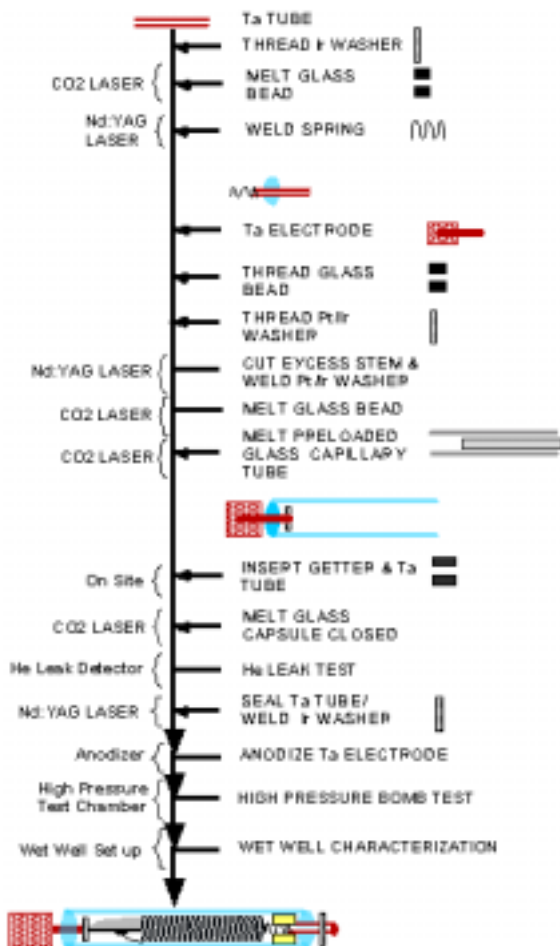


Figure 3. Order of component assembly (the electronic subassembly is made separately and preloaded into the glass tube that forms the capsule walls).

Each of the numbered steps shown in Figure 2 has certain enabling and quality control aspects:

1. The most difficult and critical hermetic seal is between the glass bead and the Ta tube (0.020" od x 0.010" id). Key factors include polishing the tube to remove longitudinal draw marks and oxidizing the surface to facilitate wetting by the molten glass. The tube with the bead on it must be rotated under the CO₂ laser beam to insure even melting. A curtain gas of argon prevents excessive oxidation of the hot Ta.
2. The first coil of the fine spring wire (0.003" thick) is welded to the side of the Ta tube just in front of the glass bead, using a tightly focused YAG laser beam. This weld must be sufficiently deep to insure good shear strength when the spring is compressed but not too deep so as to weaken the wire.
3. The Ta electrode is fixtured in a chuck via a collet made of Ta to prevent contamination of the metal surface that must eventually be anodized. Its wire stem (0.010" thick) is preloaded with a glass bead and the Pt-Ir washer. The washer is positioned at the correct distance along the stem. A single pulse from the YAG beam at a 45° angle to the stem simultaneously cuts the stem off and welds it flush with inside facing surface of the Pt-Ir washer.
4. The loose glass bead on the Ta stem is melted onto the stem at the proper position while turning the chuck under the CO₂ laser beam. Similar considerations apply as in step 1 but they are less critical because of the smaller circumference of this seal.

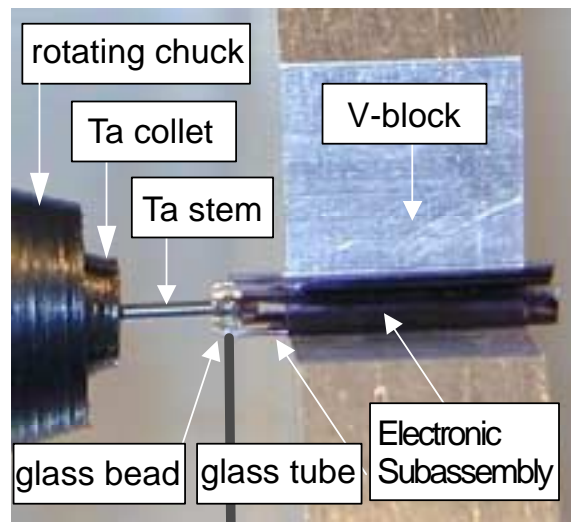


Figure 4. Formation of the open-ended capsule by picking up the stationary glass tube onto the rotating glass bead as the laser beam (red line) melts the end of the tube onto the bead.

5. The capsule is formed by melting a precut length of glass capillary tubing onto the glass bead. In the original process, much of the parts handling arose from the practice of mounting both the capillary and the Ta stem with glass bead into separate chucks that were axially aligned and synchronously rotated under

the CO₂ laser beam. Figure 4 illustrates a novel fixturing scheme whereby the stationary glass tube can be picked up by the rotating glass bead as the end of the tube melts and touches the bead. The glass tube rests in a polished V-block that keeps it in axial alignment with the bead until it attaches to and self-centers on the molten glass bead.

6. The capsule is closed by melting the opposite end of the glass tube to the glass bead affixed to the Ta tube while both parts are rotated synchronously under the CO₂ laser beam. The two chucks are positioned horizontally so as to compress the spring against the electronic subassembly, which is seated against the Pt-Ir washer at the far end.
7. Before final closure of the Ta tube, the capsule is leak-tested and back-filled as described below. The final cut-and-weld operation is similar to step 2. A single pulse from the YAG laser cuts, seals and welds the end of the Ta tube to the previously mounted Ir washer, which forms the return electrode.

III. VACUUM TESTING AND BACK-FILLING

One key objective of the workstation was to include means to test the hermeticity of the welds and backfill the capsule with dry, inert gas without dismounting any parts. This is achieved by incorporating a vacuum seal and port into the chuck that holds the Ta tube. After completing the glass seals, the port on the chuck is connected to a gas manifold that first connects the chuck to the vacuum inlet of a conventional helium leak-tester. After drawing a vacuum in the capsule via the Ta tube, helium is sprayed onto the outside of the seals to determine if any can be detected by the mass spectrometer in the leak-tester (sensitivity limit 2×10^{-11} cc atm/s). The manifold is then switched to backfill the capsule with dry nitrogen gas at approximately atmospheric pressure. The inert gas is sealed into the capsule as the Ta tube is welded shut by the YAG laser in step 7 (above). The finished BION is then subjected to a high pressure bomb test (160atm in saline for 24h) that causes rapid catastrophic failure of glass seals that happen to incorporate scratches or other stress risers that might make them prone to eventual failure.

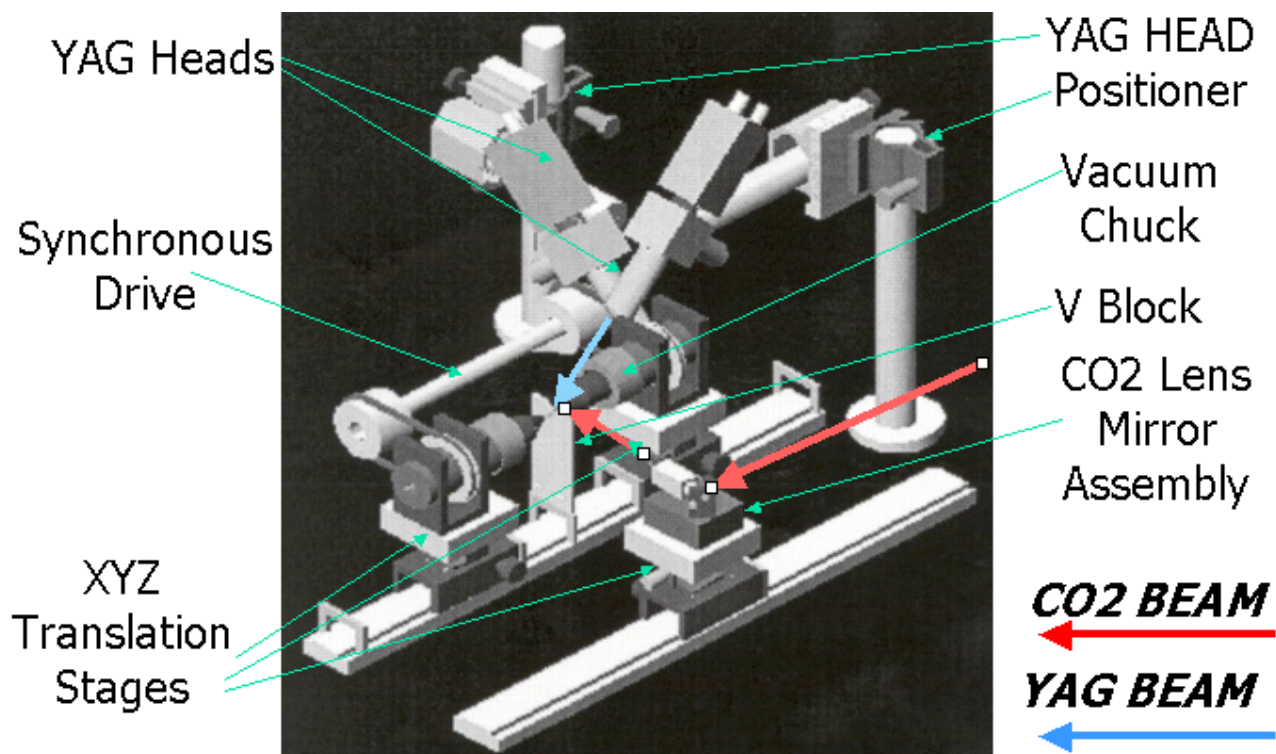


Figure 5. The integrated workstation is constructed largely from commercial optical micropositioning equipment mounted on a conventional optical bench. The two rotating chucks are driven by timing belts from a common gear train to assure synchronous rotation. The chucks and the beam forming lens and mirror for the CO₂ laser are mounted on translation stages that permit fine alignment initially and on rack-and-pinion carriages that permit rapid horizontal movement of the components to preset locations demarcated by mechanical stops. Ancillary equipment not shown includes gas manifolds for curtain gas, leak-testing and back-filling and video cameras to observe weld processes. The entire assembly is located in a light-tight Class III laser enclosure with a vertically sliding front door equipped with interlocks to prevent inadvertent exposure to the laser beams.

IV. INTEGRATED WORKSTATION

The overall plan of the workstation is shown in Figure 5. Horizontal rails equipped with rack-and-pinion gears are used to position the parts under the appropriate laser beams for each weld. By judicious placement of the laser beams and carriages, all of the YAG and CO₂ laser welds (except the spring weld) are made in approximately the same location. This facilitates the prepositioning of ancillary elements (not shown) for creating the curtain gas and capturing a video image to visualize the parts alignment and welds as they form. One YAG head is oriented at a 90° angle to the horizontal axis to weld the spring to the Ta tube (step 2 above). The other YAG head is aligned for so as to perform both of the combined cutting and welding operations (steps 3 and 7 above). The location of the CO₂ laser welds is set by the horizontal position of the mirror and lens assembly required to deflect, center and focus the infrared beam perpendicular to the weld sites. All carriages and laser heads have multiaxis fine-positioning adjustments required for the initial alignment of the workstation, but these are intended to be left fixed during normal operation.

V. DISCUSSION

Each of the weld processes was individually validated using the same equipment that is integrated into the workstation. The integrated workstation was still under construction at the time of this writing, so no process time and yield values were yet available. The package forming methods appear to be readily scaleable to other package dimensions that may be required to incorporate additional electronic functions for sensing and bi-directional telemetry that are now under development [3].

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